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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,953	02/22/2002	William J. Hennen	4428.2US	6427

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EXAMINER

CHEN, STACY BROWN

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 01/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/081,953	<b>Applicant(s)</b> HENNEN ET AL.	
	<b>Examiner</b> Stacy B. Chen	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 18-22 is/are rejected.
- 7) ☒ Claim(s) 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicant's response filed November 15, 2005 is acknowledged and entered. Claims 1-22 remain pending and under examination.

#### *Claim Rejections - 35 USC § 102 – Response to Applicant's Arguments*

2. The rejection of claims 1-3, 7-16, 18-22 under 35 U.S.C. 102(b) as being anticipated by Tokoro (5,080,895) is maintained for reasons of record. Applicant's arguments have been carefully considered but fail to persuade. Applicant's substantive arguments are primarily directed to the following:

❖ Applicant argues that the description of Tokoro is limited to exposing a chicken to antigens that purportedly result in the presence of a "transfer factor-like component" in eggs that are laid by a chicken. As Applicant has argued previously, the antigens that Tokoro uses are not of the types that induce a T-cell immune response, which is required for real transfer factor to be present. The "transfer factor-like component" is not real transfer factor, evidenced by several literature references that support this statement, all of record.

- In response to Applicant's argument, the Office recognizes that the particular ETEC antigens used by Tokoro are not of the type that induce a T-cell immune response. If a chicken were raised in a sterile environment and only ever administered the exact ETEC antigens that Tokoro describes, then Applicant's argument would be persuasive. However, that is not the case. Tokoro's disclosure is not limited to sterile environments.

- ❖ Applicant argues that a “transfer factor-like” substance, such as the “unknown food factor” mentioned in Tokoro (col. 7, lines 51-53) or nucleosides that have molecular weights of less than about 2 kD may cause a non-specific improvement in a treated animal’s immune system response. However, Applicant argues that the “transfer factor-like” substance, such as the “unknown food factor” is incapable of causing the immune system of a treated animal to elicit a specific response to a particular antigen, while transfer factor is capable of eliciting a specific response from the immune system of a treated animal. Applicant asserts that Tokoro teaches that the “transfer factor-like” substance is not transfer factor. Applicant points to Tokoro’s teaching that “the immunological functions of the transfer factor-like component....are not known” (col. 7, lines 44-47).
  - In response to Applicant’s argument, Applicant has provided no evidence that the composition of Tokoro (taken from egg extracts of hens that are naturally exposed to antigens that induce T-cell immune responses) does not contain transfer factor that induces an immune response specific to a particular antigen. Further, just because Tokoro is ignorant of the immunological functions of the transfer factor-like component, does not change the function of the transfer factor in the composition that is necessarily present.
- ❖ Applicant argues that the burden of inherency is on the examiner. Specifically, it is the examiner’s burden to show that the chickens of Tokoro were necessarily exposed to an antigen that caused a T-cell mediated immune response in the chickens. Applicant points to the MPEP 2112 which explains that the fact that a certain result or characteristic may

occur or be present in the prior art is not sufficient to establish inherency of that result of characteristic. Applicant argues that a chicken would not necessarily be exposed to some antigen that would induce a T-cell response. Chickens are raised in controlled environments that prevent exposure of a chicken to any antigens, including Newcastle diseases virus. Applicant argues that Tokoro does not expressly or inherently describe that chickens must be exposed to any other antigens. Applicant points to Tokoro's teaching (col. 2, lines 54-60) that rats may be "germ-free", which implies a sterile environment.

- In response to Applicant's argument, the Office maintains that Tokoro's chickens were exposed to antigens that induced T-cell immune responses. The reason that chickens are immunized with Newcastle vaccine is that chickens are exposed to NDV. If chicken accommodations were sterile, then no vaccination would ever be required. The Office maintains that Tokoro's chickens were undoubtedly exposed to a pathogen at some point before laying eggs that induced an immune response. Unless Tokoro housed the chickens in a completely sterile environment, one would expect that Tokoro's chickens had had a T-cell immune response to some antigen.
- Tokoro's reference to germ-free rats is in no way limiting the environment of Tokoro's hens to sterile only. Further, the context in which the germ-free rats are mentioned is not directly related to the method and composition described by Tokoro. The comments are in reference to summarizing the prior art.

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- One of ordinary skill in the art would recognize that Tokoro's chickens were at some point exposed to antigens that induce T cell immune responses, thus necessarily producing transfer factor.
- ❖ Applicant argues that Tokoro's description is limited to generating antibodies with antibodies that are not capable of inducing a T-cell mediated immune response.
  - In response to Applicant's argument, the emphasis on antibodies in Tokoro's description does not mean that the chickens did not actually have T-cell responses.
- ❖ Applicant argues that Tokoro does not expressly or inherently describe that the transfer factor-like component of the eggs would be useful for eliciting a T-cell mediated immune response. Applicant argues that claims 19 and 21 are allowable since Tokoro includes no express or inherent description that there is a sufficient amount of transfer factor in any of the compositions disclosed therein to cause an animal to which the composition is administered to elicit a T-cell mediated immune response *in vivo*. Applicant argues that claim 22 is allowable since Tokoro includes no express or inherent description that administration of an extract of the eggs disclosed therein to a treated animal would enhance the ability of the immune system of the treated animal to elicit an increased T-cell mediated immune response relative to the treated animal's normal T-cell mediated immune response to at least one antigenic agent.
  - In response to Applicant's argument, the yolk or albumen of Tokoro's immunized hens is administered to other animals to induce an immune response. The fact that Tokoro does not recognize that there is a T-cell response, does not mean that

there was no T-cell response. Even if Tokoro did not appreciate that transfer factor was in the egg yolks, the egg yolks were still administered to animals to induce an immune response against pathogens.

- ❖ Applicant asserts that claims 2, 3, 7-16, 18, 19 and 22 are allowable because they depend from claim 1, which is allowable. Claim 19 is allowable because Tokoro does not teach that there is a sufficient amount of transfer factor in any of the compositions disclosed therein to cause an animal to elicit a T-cell response *in vivo*. Claim 20 is allowable because Tokoro does not teach that the administration of the extract of the eggs would enhance the ability of the immune system of the treated animal to elicit an increased T-cell mediated immune response. Further, claim 21 is allowable because it depends from claim 20, which is allowable. Claim 21 also is allowable because Tokoro does not teach that there is sufficient amount of transfer factor in any of the compositions disclosed therein to cause an animal to which the composition is administered to elicit a T-cell mediated immune response *in vivo*.

- In response to Applicant's assertions, claims 2, 3, 7-16, 18, 19 and 22 are not allowable because claim 1 remains rejected. Regarding claims 19, 20 and 21, these points have been addressed above. Tokoro's ignorance of the presence of transfer factor in the chicken eggs does not change the fact that transfer factor was necessarily present in eggs from chickens exposed to naturally-present pathogens that induce T-cell responses.

In summary, the claims remain rejected for reasons of record. In summary, the Office holds the position that Tokoro's chickens were at some point exposed to antigens that induced T-

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cell responses. Since Tokoro's chickens laid eggs from which yolks were taken and administered to animals, the transfer factor is expected to have been administered to the animals, thus increasing their T-cell repertoire. Tokoro's composition and method of use read on the present invention.

***Claim Rejections - 35 USC § 103 – Response to Applicant's Arguments***

3. Claims 4-6 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Tokoro (5,080,895) as applied to claims 1-3, 7-16 and 18-22 above, and further in view of Kirkpatrick *et al* (5,840,700), for reasons of record. Applicant's arguments have been carefully considered but fail to persuade. Applicant's arguments are primarily directed to the following:

- ❖ Applicant argues that claims 4-6 are allowable, among other reasons, for depending directly from claim 1, which is allowable.
  - In response to Applicant's arguments, claims 4-6 are not allowable because claim 1 is not allowable.
- ❖ Applicant argues that claims 4-6 are additionally allowable because one of ordinary skill in the art would not have been motivated to combine teachings from Tokoro and Kirkpatrick since the teachings of Kirkpatrick may be effectively administered non-orally, as they include transfer factor that is very pure, while the compositions of Tokoro may not be effective when administered non-orally, since they are intended to treat intestinal pathogens. Further, one of ordinary skill in the art would readily recognize that the "purification" processes of Tokoro would not remove large molecules such as antibodies from resulting compositions.



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- In response, Applicant's arguments fail to persuade. Although Tokoro does not explicitly say that transfer factor is present in their product, or perhaps does not know that transfer factor is present, one would have been motivated to formulate their product for different applications because Tokoro suggests that any appropriate route for administration be used (col. 5, lines 29-34).
- Further Kirkpatrick's teachings are not limited to non-oral routes of delivery. Kirkpatrick teaches that transfer factor can be administered intravenously, intramuscularly, subcutaneously or orally. One would have been motivated to administer the transfer factor via a variety of routes depending on the subject receiving it. One would have had a reasonable expectation of success that the product of Tokoro would have been able to formulate it because Kirkpatrick formulates transfer factor in various mediums.

### ***Conclusion***

4. Claim 17 remains free of the prior art, but objected to for depending from a rejected claim.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Stacy B. Chen  
January 12, 2006